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10/760,151

01/15/2004

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

08/22/2007

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/760,151

Applicant(s)

FILSOUFI, FARZAN

Examiner

Paul B. Prebilit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15-19 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-9,12,13,15-19 and 42-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 15, 2007 has been entered.

***Election/Restrictions***

Claims 3, 4, 10, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 22, 2005.

***Claim Objections***

Claims 6, 12, and 13 are objected to because of the following informalities:

Upon review of the claims, the Examiner discovered some objectionable language that should be changed to make the claim language clearer.

In claim 6, line 2, "the free margin" lacks clear antecedent basis.

In claim 12, line 2, the language "normally function leaflet" is grammatically awkward and could be changed to ---normally functioning leaflet--- in order to make this language clearer.

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In claim 13, line 2, the language "an area at least about 25 mm<sup>2</sup>" is grammatically awkward and should be changed to ---an area of at least about 25 mm<sup>2</sup> ---- in order to overcome this objection.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Upon careful further review of the claims and specification, the Examiner concluded that the language "the structure is configured to be non-attachable to an annulus of the valve" lacks original support and appear nonenabled. In particular, this language was added to the present application on March 24, 2006 that is after the filing date of this application of January 15, 2004. In particular, a structure configured into a nonattachable configuration may even preclude the very structure disclosed in the present specification because the structure is clearly capable of attachment to a leaflet so it would also be attachable to a leaflet via glue or sutures. In other words, there is no original disclosure that describes a structure that cannot be attached to an annulus. Rather, it is merely utilized in a way that it is attached to the

leaflet but not to the annulus. An RCE, as that filed on April 24, 2006, cannot be used as a means to add new subject matter; see 37 CFR 1.114.

Claims 1, 5-9, 12, 13, 15-19, and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is unclear what "an effective valve area" is because it has not been clearly and adequately described in the specification; see paragraph [0023] of the present specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-9, 12, 13, 15-19, and 43-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Due to the fact that the "effective valve area" has not been adequately explained, the Examiner asserts that the claim scope is unclear in that it is not clear what would fall within the claim scope and what would not.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

As an alternative to the Section 112, first paragraph rejection pertaining to a non-attachable configuration, the Examiner asserts that even if the Applicant can show that there is inherent support that the claim language would still lack antecedent basis from the specification.

Claim 18 invokes a Section 112, sixth paragraph interpretation in that it sets forth "fixation means for attaching." However, claim 19 does not invoke Section 112, sixth paragraph because it is limited by sufficient structure; see MPEP 2181 to 2186.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7-9, 12, 16-19, and 43-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Dardik et al' (US 3,988,782). Dardik anticipates the claim language where the graft of Dardik is considered to be at least semi-rigid to the extent claimed because it is hardened and even provided with a backing to improve its integrity (see column 7, lines 18-21). In other words, it is capable of being attached to a leaflet to the extent that the functional language implies; see Figures 5 and 6 and column 5, line 15 to column 6, line 61.

It is noted that a wide variety of rigidities is considered suitable for the presently disclosed invention ranging from rigid to flexible and elastic; see paragraph [0042]. Therefore, the Examiner asserts that the Dardik material is rigid to semi-rigid to the

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extent required by the claims because it reasonably appears to be able to function as claimed in that it is to be used in a similar environment.

With regard to claim 18, the suture of Dardik is a fixation means as claimed; see claim 19.

With regard to claim 43, the claim is indefinite in scope but the disclosed invention reasonably appears to be identical to that disclosed by Dardik. Therefore, the claimed invention reasonably appears to be identical to Dardik.

Claims 1, 5, 6-9, 12, 16-19, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Saxon (US 5,725,577). Saxon anticipates the claim language in that the device thereof would be inherently capable of functioning as the functional language implies; see Figure 6 and the abstract.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dardik et al (US 3,988,782) alone. Dardik meets the claim language as explained in the Section 102 rejection utilizing Dardik, but fails to disclose the particular dimensions as claimed. However, when the only difference between the prior art and the claims is a recitation of some relative dimensions and the prior art device would not perform differently than the claimed device, the claimed device would have been

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considered *prima facie* obvious to an ordinary artisan. The following is an excerpt from MPEP 2144.04:

*In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

### ***Response to Arguments***

The Applicant failed to present arguments pertaining the present claims and how they are rewritten to overcome the applied prior art.

### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.



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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/  
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